IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appl No.	: 10/562,368	Confirmation No. 6260
Appellant	: Maurice Loretti et al.	
Filed	: June 8, 2006	
Title	: MULTILAYER FILM	
TC/A.U.	: 1794	
Examiner	: Ahmed, Sheeba	
Docket No.	: 1131-16-PCT-PA-TD	
Customer No.	: 22145	

SUPPLEMENTAL FILING

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18200 Von Karman, Suite 725
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June 17, 2011

Commissioner:

As indicated during the Oral Hearing of April 13, 2011 in connection with the above-identified application, wherein reference to the instant specification were given as paragraph numbers, as they appear in US publication No. 2007/0048510 ("the '510 publication"), Appellant hereby forwards corresponding pages and line numbers from the original application for the Board's reference.

Enclosed in Appendix 1, please find the cited paragraphs from the '510 publication that were discussed by Appellant's undersigned attorney during the Oral Hearing and the corresponding page and line numbers as they appear in the originally filed specification.

Should the Commissioner wish to speak with Appellant's attorney, the Commissioner is invited to contact the undersigned at the telephone number identified below.

Respectfully originally filed,
KLEIN, O'NEILL & SINGH, LLP

By _____
Tom H. Dao
Reg. No. 44,641
949/955-1920

Application number 10/562,368
Supplemental references

Appendix 1

1. The reference to EP 0 965 443 A1, cited in paragraph [0011] of the '510 publication, is found on page 3, line 19-23 of the originally filed specification.

2. The following citation taken from paragraph [0016] of the '510 publication can be found on page 4, lines 5-11 of the originally filed specification:
Basic requirements for a plastic bag system . . . include minimized drugs absorption on the interior side, minimized water loss of the contents through the plastic film, sterilizability of contents and container/film material as well as maximized protection of the contents against oxidation by environmental oxygen.

3. The following citation taken from paragraph [0018] of the '510 publication can be found on page 4, lines 24-29 of the originally filed specification:
Plastic films used in the pharma industry usually show little or no water adsorption from the environment and the contained solution at 23°C before sterilization. During sterilization at 121°C, the films adsorb significant amounts of water both from the environment and the solution by which oxygen permeability of the film is dramatically increased.

4. The following citation taken from paragraph [0037] of the '510 publication can be found on page 8, line 27 to page 9, line 11 of the originally filed specification:
It has been found that common EVOH layers during sterilization at 121°C absorb a serious amount of water. According to the present invention the presence of an outer layer, which allows desorption of water absorbed by the intermediate layer during the sterilization process helps to reduce the specific humidity of the intermediate layer and thus, improves the oxygen barrier function of the film by significantly reducing the oxygen permeability of the intermediate layer. A specific humidity of the intermediate layer after storing the multilayer film in an environment having a relative humidity for example of 70% at 23°C results in an oxygen transmission rate at 23°C through the multilayer film of less than 0.7 ml/m^{2}d. This relation between specific humidity of the intermediate layer, oxygen transmission rate through the multilayer film and the anti-aging effect on the contents of the container has never been disclosed nor considered in the prior art.

5. The following citation taken from paragraph [0038] of the '510 publication can be found on page 9, lines 18-26 of the originally filed specification:
(multilayer film A1). The specific humidity of its intermediate EVOH-layer corresponds to around 50% relative humidity of the environment and it exhibits an oxygen permeability at 23°C of less than 0.4 ml/m^{2}d. On the contrary, multilayer film A2 as a

comparative example, differing from A1 in that the outer layer consists of PP allows desorption of water to a significantly less extent. The specific humidity of the intermediate layer corresponds to close to 80% relative humidity, and oxygen permeability at 23°C is significantly greater than 0.7 ml/m^{2}d.

6. The following citation taken from paragraph [0039] of the '510 publication can be found on page 9, line 28 to page 10, line 2 of the originally filed specification:
In a preferred embodiment the oxygen transmission rate at 23°C through the multilayer film is less than 0.4 ml/m^{2}d. Said preferred rate can be achieved by allowing to reduce the specific humidity of the intermediate layer.

7. The following citation taken from paragraph [0048] of the '510 publication can be found on page 12, lines 22-29 of the originally filed specification:
According to the invention, when a container is sterilized, the outer layer must permit to evaporate residual humidity which has been introduced into the multilayer structure and therefore humidifies the intermediate layer. Preferred in the sense of the invention is an outer layer comprising or substantially consisting of polyethylene terephthalate (PET) homopolymer and/or polyethylene terephthalate (PET) copolymers. Useful copolymers are commercially available such as Ecdel® type, from Eastman Chemical or Hytrel® type from DuPont.

8. The following citation taken from paragraph [0051] of the '510 publication can be found on page 13, lines 12-28 of the originally filed specification:
FIG. 3 gives the results of a long-term comparative experiment illustrating the oxidation of solutions of high concentrated (approx. 2.2 g/l) vitamin C at 23°C in containers made of different multilayer films . . .At this time, the solution contained in a bag of a multilayer film (A2), differing from A1 in that the outer layer was made of PP instead of PET, thereby being less effective in desorption of water, contained but 35% of c_0 of vitamin C. A solution contained in a plastic bag of a film without the intermediate layer, consisting of an inner layer made of PP and SEBS and an outer layer made of PET (A4) had lost practically all of its original content of vitamin C during the course of the experiment. The superiority of multilayer films according to the invention in preserving of solutions sensitive to oxidation is thereby illustrated.

9. The following citation taken from paragraph [0052] of the '510 publication can be found on page 14, lines 1-5 of the originally filed specification:
The oxygen transition rate of the multilayer film and accordingly that of the intermediate layer depends on the moisture content (specific humidity) inside the resin. Therefore the structure of the outer layer controls the oxygen transmission rate indirectly by its own water vapor transmission rate.

KLEIN, O'NEILL & SINGH, LLP

18200 Von Karman Ave., Suite 725
Irvine, CA 92612
Tel: 949-955-1920
Fax: 949-955-1921

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